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REMARKS

Applicants have received and carefully reviewed the Final Office Action mailed December 8, 2003. A response to such Action was filed March 5, 2004. The Examiner issued an Advisory Action on April 12, 2004 in which it was stated that the Amendment After Final was not entered. This Amendment is submitted with a Request for Continued Examination (RCE), and Applicants request withdrawal of finality of the last action and entry of the present Amendment. Claims 1-15, 17-22, 24-42, 44-48, 50-56, 58 and 59 remain pending, with claims 1-15, 17-22, 24-42, 44-48, 50, 53-56 and 58-59 rejected and claims 51 and 52 objected to. Claims 1, 24, and 31 have been amended, new claims 61-63 have been added, Figure 5 has been amended, and new Figure 6 has been added. Support for the amendments is found in the specification as originally filed, for example, at page 8, lines 9-10 for the claims, and at page 10, lines 1-8 for Figures 5 and 6. No new matter has been added.

In the Office Action, the drawings were objected to under 37 C.F.R. §1.83(a) for not showing every feature of the invention specified in the claims. Specifically, the Examiner argued that the coil, as claimed in claim 52, is shown in the drawings alongside the inner liner 212, rather than between the inner liner and outer cover, as is recited in the claim. As shown in the attached proposed drawing correction, Fig. 5 has been amended to show the embodiment in which a braid is positioned between the inner and outer covers. New Fig. 6 has been added to show the embodiment in which a coil is positioned between the inner and outer covers. Withdrawal of the drawing objection is respectfully requested. Further, formal drawings are submitted concurrent with this Amendment.

In the Office Action, claims 1, 2, 13, 19, 20, 24, 27, 31, 40, 46, 47, 50, 53-56, 58 and 59 were rejected under 35 U.S.C. §102(b) as being anticipated by JP 05-220225 in view of Samson (U.S. Patent No. 5,702,373). Applicants respectfully traverse this rejection.

Independent claims 1, 24 and 31 recite a knit tubular member formed from a plurality of interlocking up and down loops that is generally <u>not</u> radially expandable. JP 05-220225 fails to teach either of these aspects of the invention. The Examiner states that the reference must be read in light of its plain meaning. There are at least three plain meanings of "knit", as shown in the attached printout from the Merriam-Webster Online Dictionary (obtainable at www.m-w.com), including (1) to tie together; (2) to link firmly or closely; and (3) to form by interlacing

yarn or thread in a series of connected loops with needles. Given the different plain meanings possible for "knit", the skilled artisan would logically turn to the figures in the Japanese reference in an attempt to determine which meaning of "knit" was intended by the reference. The figures, especially Figures 5A and 7A, show the wires in a woven or crisscross pattern. The figures in JP 05-220225 clearly do not show interlocking up and down loops, as is recited in the instant claims.

Applicants have obtained a machine translation of the entire Japanese reference (available from the Japanese Patent Office web site at http://www19.ipdl.jpo.go.jp/PA1/cgibin/PA1INIT?1084198718441). A copy is enclosed for the Examiner's convenience. In the detailed description, the method of manufacturing the catheter is described as including forming the wire layer by turns. See pages 4, 5, and 10 (emphasis added). This description follows what is shown in the figures, which is a wire net that is woven or braided. Additionally, there is a reference to the different pitches in the tight and loose sections. Applicants submit that the term "pitch" is commonly used to denote the number of threads per inch in a woven material. Thus, when the figures of the Japanese patent are viewed in light of the specification, it is clear that the term "knit" is being used for its meaning of "to link firmly or closely", meaning the wire is actually woven or braided. There is no teaching or suggestion in the Japanese patent of a knit tubular member formed from a plurality of interlocking up and down loops, where the knit is generally not radially expandable, as is instantly claimed.

The Examiner appears to be selecting a definition of "knit" that is contrary to the figures in the reference in order to assert the reference teaches the claimed invention. Applicants submit that without using the instant specification for guidance, the skilled artisan would interpret the "knitted" reinforcing layer of JP 05-220225 as a woven or crisscross pattern, as is clearly shown in the reference's figures. While the English translation of the Japanese abstract uses the word "knitted", there is no teaching or suggestion in the abstract that the reinforcing layer is formed from a plurality of interlocking up and down loops, as is recited in the claims.

Additionally, JP 05-220225 does not teach a tubular member formed of a plurality of interlocking loops that is generally <u>not radially expandable</u>, as is also recited in the claims. To the contrary, one of skill in the art, upon reviewing the English abstract and figures, would likely conclude the reinforcing layer 35 <u>was</u> radially expandable in order to achieve the transition from the area of tightly woven wires 35A to loosely woven wires 35B. The Examiner has not

indicated what language in the English abstract or which figure is being relied on for a teaching of the wire mesh not being radially expandable.

In the Advisory Action mailed April 2, 2004, the Examiner stated that a knitted layer is generally not radially expandable because the loops do not allow the knit free expansion. However, no reference or other support for this assertion was provided. The only support for this assertion appears to be Applicants' own specification. If this argument is maintained, Applicants respectfully request the Examiner provide a reference or other teaching to support this assertion. The Examiner also questions Applicants' use of both "generally not radially expandable" and "non-radially expandable" in previous arguments. The Examiner's attention is directed to page 8, lines 17-20 of the specification where the amount of expansion is defined. The claims must be read in light of the specification, and the specification does provide a clear definition for the phrase in question.

As the English language Abstract of JP 05-220225 does not teach a non-radially expandable tubular member made of interlocking up and down loops, it fails to teach every element of the invention as claimed in independent claims 1, 24 and 31. Applicants firmly believe claims 1, 24, 31 and 54-56 are in condition for allowance. Claims 2, 13, 19 and 20 depend from claim 1 and contain significant additional elements; claim 27 depends from claim 24 and contains significant additional elements; and claims 40, 46, 47, 50, 53, 58 and 59 depend from claim 31 and contain significant additional elements. Applicants firmly believe that these claims also are in condition for allowance for at least the reasons stated above.

In the Office Action, claims 1-5, 13, 14, 18-20, 24-27, 31-33, 40, 41, 45-47, 50, 53-56, 58 and 59 were rejected under 35 U.S.C. § 102(e) as being anticipated by Leoni (U.S. Patent No. 5,772,681). Applicants respectfully traverse this rejection.

Leoni teaches a dilation catheter having an expandable balloon section. The balloon section has a reinforcement net preventing over-expansion of the balloon. The reinforcement net is made of metallic monofilaments moveable with respect to each other at the crossover points to allow expansion of the balloon section. Applicants respectfully assert that Leoni fails to teach that which is claimed in the current invention. Namely, Leoni fails to teach a knit tubular member that is generally not radially expandable. The Examiner states that Leoni teaches an "outer cover that is generally not expandable in the section adjacent to the balloon section" (page 3, lines 1-2 of Office Action). However, the claims recite, "the knit tubular member ... is

generally not radially expandable" (claims 1, 24 and 31). Therefore, in the instant claims, it is the knit tubular member, not the cover or outer member, that is not radially expandable. The part of Leoni's device that is not expandable appears to be the pipe 9. While Leoni does not clearly describe the pipe 9, the statement that "the middle section also comprises a non-expandable part having a greater length than the balloon section" (see claims 4 and 9) indicates the non-expandable part is the pipe 9. It certainly cannot be the balloon section, because the balloon is clearly described as being radially expandable (see FIG. 2). Additionally, Leoni describes the non-expandable part as having a greater length than the balloon section, so the non-expandable part, by definition, must be some part other than the balloon section.

Further, there is no motivation for one to modify the device of Leoni to make the metallic mesh non-expandable. In the instantly claimed invention, the knitted tubular member that is generally not radially expandable provides strength and flexibility to the elongate shaft, wherein the purpose of the metallic mesh in Leoni's device is to allow the balloon within the mesh to expand to the configuration of a blood vessel, but to prevent over-expansion (column 2, lines 32-37). Therefore, Applicants assert that Leoni fails to teach the elements of the presently claimed invention, namely a knit tubular member formed by a plurality of interlocking loops that is not generally radially expandable.

In the Advisory Action mailed April 2, 2004, the Examiner maintains that Leoni teaches a knit member that is generally not radially expandable. This assertion is directly contradicted by the express teachings of Leoni. In column 3, lines 58-61, Leoni specifically teaches that the contact points in the mesh are moveable with respect to each other "during expansion of the balloon section." Leoni also describes the net 2 as covering "the expanding object, i.e. the balloon section 11" (see column 4, lines 28-29). Additionally, FIG. 2 of Leoni shows and is clearly labeled "RADIAL EXPANSION" of the net covered balloon section. The only references in Leoni to "non-expandable" are in column 3, line 19, claim 4 and claim 9. In each instance, Leoni is referring to "a non-expandable part" having a "greater length than the balloon section." However, the reinforcement net, which can be helically wound, knitted or braided, is described as "extending helically around the longitudinal axis of the balloon section." See column 3, lines 54-57. Additionally, FIG. 3 clearly shows the net 2 surrounding the balloon section 11. Thus, any "non-expandable part" having a "greater length than the balloon section" cannot be interpreted as being the net because the net is only present in the balloon section. It is

unfortunate that Leoni does not specifically describe the "non-expandable part" recited in the claims. However, one of ordinary skill in the art, upon reading the entire Leoni disclosure, would interpret the pipe 9 as being the only logical "non-expandable part" in the catheter. If this rejection is maintained, Applicants respectfully request the Examiner point out specifically where in the Leoni reference support can be found for a non-expandable net.

Applicants respectfully assert that claims 1, 24 and 31 contain at least one element not taught in Leoni. Therefore, they are believed to be in condition for allowance. Claims 2-5, 13, 14, 18-20 and 54-56 depend from claim 1 and contain significant additional elements, claims 25-27 depend from claim 24 and contain significant additional elements, and claims 32, 33, 40, 41, 45-47, 50, 53, 58 and 59 depend from claim 31 and contain significant additional elements. Therefore, these claims are also believed to be in condition for allowance.

Claims 6-12, 15, 21, 28-30, 34-39, 42 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni and further in view of Andersen et al. (U.S. Patent No. 5,674,276). Applicants respectfully traverse this rejection. As stated above, neither JP 05-220225 nor Leoni teach the claimed invention, and Andersen et al. fail to remedy the shortcomings of JP 05-220225 or Leoni. For the reasons stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Claims 17, 22, 44 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over JP 05-220225 or Leoni as applied to claims 54, 1 and 58 respectively above, and further in view of Jang et al. (U.S. Patent No. 4,898,591). Applicants respectfully traverse this rejection. As stated above, neither JP 05-220225 nor Leoni teach the claimed invention, and Jang et al. fail to remedy the shortcomings of JP 05-220225 or Leoni. For the reasons stated above, Applicants believe the rejection should be withdrawn, asserting that the stated claims are in condition for allowance.

Appl. No. 09/097,023 RCE dated May 10, 2004 Reply to Final Office Action of December 8, 2003

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully Submitted,

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By their Attorney,

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Attachment: Replacement Drawing Sheets

Machine Translation of JP-05-220225

Printout of Merriam-Webster Online Dictionary

Merriam-Webster Online Dictionary

9 entries found for knit.

To select an entry, click on it.

knit[1,verb]	▲ Go	.
knit[2,noun]		
close-knit		
double knit		
knit stitch	,	
tight-knit	~	

Main Entry: ¹knit ≰

Pronunciation: 'nit

Function: verb

Inflected Form(s): knit or knit ted; knit ting

Etymology: Middle English knitten, from Old English

cnyttan; akin to Old English cnotta knot

transitive senses

1 chiefly dialect: to tie together

2 a: to link firmly or closely < knitted my hands > b: to cause to grow together < time and rest will knit a fractured

bone > c: to contract into wrinkles < knitted her brow >

3: to form by interlacing yarn or thread in a series of connected loops with needles

intransitive senses

1: to make knitted fabrics or objects

 $\mathbf{2}$ \mathbf{a} : to become compact \mathbf{b} : to grow together \mathbf{c} : to become drawn together

- knit·ter noun

[JP,05-220225,A]

* NOTICES *

Japan Patent Office is not responsible for any damages caused by the use of this translation.

- 1. This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.**** shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

CLAIMS

[Claim(s)]

[Claim 1] It is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer, between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] The catheter characterized by consisting of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[Claim 2] It is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer, between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] The catheter characterized by consisting of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit.

[Claim 3] between inner tube parts and outer tube parts -- much more -- since -- the catheter which the becoming reinforcement layer is infixed, and this point does not have the abovementioned reinforcement layer, but is further characterized by to fix the edge by the side of the tip of said reinforcement layer to an inner tube part. [in / it is the catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section]

DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Industrial Application] This invention relates to a catheter.

[0002]

[Description of the Prior Art] The catheter 1 as shown in <u>drawing 1</u> is led to a guidewire etc., and is inserted into coelomata, such as a blood vessel, and attainment of it to the target part is enabled, the direction of the tip being controlled.

[0003] So, this catheter 1 is required to have the torsional rigidity which becomes size so that it

may be possible to twist the base of the body section 2 and to orient that point 3. moreover, the point 3 -- the purpose part -- insertion -- it is possible to give an easy configuration easily, and flexibility is required of a point 3 so that the point 3 at the time of insertion may deform easily along with insertion path change of a blood vessel etc. and damage may not be done to walls, such as a blood vessel.

[0004] drawing 2 -- a point -- flexibility -- having -- and -- size -- the conventional catheter 4 which comes to have torsional rigidity is shown -- it is a fracture Fig. a part. The catheter 4 forms the body section 8 which is torsional rigidity and which becomes size by infixing the wire layer 7 between the flexible inner tube part 5 and the flexible outer tube part 6. Furthermore, the comparatively flexible point 9 is connected to the edge at which this catheter 4 removed the outer tube part 6 of the above-mentioned body section 8 in part.

[0005] drawing 3 -- a point -- flexibility -- having -- and -- size -- other conventional catheters 10 which come to have torsional rigidity are shown -- it is a fracture Fig. a part. After this catheter 10 had the 1st wire layer 12 formed from the end face of the flexible inner tube part 11 to tip this side, and it turns it up from that tip this side and it has the 2nd wire layer 13 again formed to a end face, it is having the flexible outer tube part 14 covered by the top face of an inner tube part 11 and both the wire layers 12 and 13.

[0006]

[Problem(s) to be Solved by the Invention] However, if it is in the above-mentioned catheter 4, a level difference is produced in the connection of the body section 8 and a point 9, it is difficult to perform insertion to a blood vessel etc. smoothly, and there is a possibility of producing a thrombus. Moreover, there is a possibility of producing balking among both, according to the faulty connection of the body section 8 and a point 9.

[0007] Moreover, since the reinforcement layer which consists of the 1st wire layer 12 and the 2nd wire layer 13 of a bilayer between the inner tube parts 11 and outer tube parts 14 from which the above-mentioned catheter 10 constitutes the body section is infixed, a catheter bore serves as smallness under the predetermined catheter outer diameter in which the thickness of a reinforcement layer becomes settled with insertion way bores, such as a blood vessel in which a large next door and a catheter are inserted. Moreover, since the thickness of the above-mentioned reinforcement layer is size, the level difference which comes size comparatively between the catheter outer diameter of the body section and the catheter outer diameter of a point is produced, and it becomes difficult to perform insertion to a blood vessel etc. Moreover, the above-mentioned catheter 10 is the top face of the inner tube part 11 which constitutes the body section, since it forms by turning up the 1st wire layer 12 and the 2nd wire layer 13, cannot form the whole continuously and cannot obtain the base material for catheters.

[0008] Moreover, while carrying out a loose thing for change of the torsional rigidity of the body section and a point and making quick responsibility of the point to rotation of the body section in order to improve the insertion workability into a blood vessel coelome if it is in a catheter, to enable prevention of sudden a point bending to the body section is desired.

[0009] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point, this invention While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The purpose is carried out for offering the catheter which can prevent that sudden a point bends to the body section.

[0010]

[Means for Solving the Problem] This invention according to claim 1 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[0011] This invention according to claim 2 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer, between inner tube parts and outer tube parts -- much more -- since -further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit. [0012] between inner tube parts and outer tube parts -- much more -- since -- the becoming reinforcement layer is infixed, this point does not have the above-mentioned reinforcement layer, but the edge by the side of the tip of said reinforcement layer is being further fixed to the inner tube part. [in / this invention according to claim 3 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section] In addition, "immobilization" said here shall paste up the edge by the side of the tip of a reinforcement layer on an inner tube part with adhesives, and also laying under the inner tube welding and the wire layer which is a reinforcement layer further at an inner tube, applying heat shall include it. [0013]

[Function] According to this invention, there is the operation effectiveness of the following ** - **

- ** between inner tube parts and outer tube parts -- much more -- since -- since the becoming reinforcement layer is infixed and it was made for this point not to have the above-mentioned reinforcement layer, while the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and an outer diameter is equalized by the body section and the point -- comparatively -- size -- it becomes possible to form a bore. [in / a catheter has a point and the body section and / this body section]
- [0014] ** Since the reinforcement layer was constituted from two steps of what is not knit with two steps or the knit thing of ** as it is dense, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, it becomes possible to prevent that sudden a point bends to the body section.
- [0015] ** The edge by the side of the tip of a reinforcement layer becomes possible [preventing the exfoliation from the inner tube part of the reinforcement layer edge in a manufacture phase] by coming to be fixed to an inner tube part.

 [0016]

[Example] The top view showing the catheter 30 which <u>drawing 4</u> (A) requires for the 1st example of this invention, the top view in which <u>drawing 4</u> (B) exfoliates and shows a part of outer tube part of this catheter 30, <u>drawing 5</u> (A), and (B) are the top views showing the

manufacture process of this catheter 30.

[0017] a catheter 30 is shown in <u>drawing 4</u> (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- smallness -- a point 31 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 32 is really formed in shaft orientations. between the flexible inner tube part 33 in the body section 31 if it is in the above-mentioned catheter 30, and the flexible outer tube parts 34 -- much more -- since -- the becoming reinforcement layer 35 is infixed and the point 32 is formed according to the unification condition of an inner tube part 33 and an outer tube part 34. Here, the reinforcement layer 35 is formed from wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side). The edge by the side of the point 32 of wire layer 35B is pasted up on the inner tube part 33.

[0018] While according to the above-mentioned catheter 30 the body section 31 and a point 32 are really formed, torsional rigidity has flexibility in a point 32 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 31 and the point 32, it becomes possible to form the bore which becomes size comparatively. If it is in the above-mentioned catheter 30 especially, by wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side) Since the reinforcement layer 35 was formed, while making quick responsibility of the point [as opposed to rotation of the body section 31 for change of the torsional rigidity of the body section 31 and a point 32] 32 as a loose thing It becomes possible to prevent that sudden a point 32 bends to the body section 31, and to prevent lock out generating of a catheter building envelope based on bending. Moreover, if it was in the above-mentioned catheter 30, since the edge by the side of the point 32 of wire layer 35B was pasted up on the inner tube part 33, it becomes possible to prevent the exfoliation from the inner tube part 33 of wire layer 35B in a manufacture phase.

[0019] Next, the manufacture approach of the above-mentioned catheter 30 is explained. First, extrusion molding of the flexible inner tube part 33 is carried out. Next, as shown in drawing 5 (A), the reinforcement layer 35 is continuously formed further in the top face of an inner tube part 33, here -- wire layer 35A with the eye of a network dense [the reinforcement layer 35] (for example, pitch P1 = 1mm), and the eye of a network -- ** (for example, pitch P2 = 10mm) -wire layer 35B is formed by turns. Next, after pasting up with adhesives the edge of wire layer 35B of the fixed section which should be removed on an inner tube part 33, a part of abbreviation center section of the above-mentioned wire layer 35B is removed as shown in drawing 5 (B). Next, extrusion molding of the flexible outer tube part 34 is carried out to the top face of an inner tube part 33 and the wire layers 35A and 35B. Next, abbreviation pars intermedia X1 of a part with wire layer 35A Abbreviation pars intermedia X2 of a part without the reinforcement layer 35 The catheter 30 which cuts, makes a part with the wire layers 35A and 35B the body section 31, and uses a part without the reinforcement layer 35 as a point 32 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 35, and a part without the reinforcement layer 35, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 35 and the pars intermedia of a part without the reinforcement layer 35"] was provided here, if it was in this example etc., and it is a catheter 30 about the reinforcement layer 35. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 30.

[0020] The top view showing the catheter 40 which <u>drawing 6</u> (A) requires for the 2nd example of this invention, the top view in which <u>drawing 6</u> (B) exfoliates and shows a part of outer tube part of this catheter 40, <u>drawing 7</u> (A), and (B) are the top views showing the manufacture process of this catheter 40.

[0021] a catheter 40 is shown in drawing 6 (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- size -- the body section 41 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 42 is really formed in shaft orientations. between the flexible inner tube part 43 in the body section 41 if it is in the above-mentioned catheter 40, and the flexible outer tube parts 44 -- much more -- since -- the becoming reinforcement layer 45 is infixed and the point 42 is formed in an inner tube part 43 according to the unification condition of an outer tube part 44. Here, the reinforcement layer 45 is formed from wire layer 45A by which the anti-point 42 side (end face side) in the body section 41 was knit, and wire layer 45B by which the point 42 side in the body section 41 is not knit. The edge by the side of the point 42 of wire layer 45B is pasted up on the inner tube part 43. Wire layer 45B which is not knit is prepared in a catheter shaft and parallel as drawing 7.

[0022] While according to the above-mentioned catheter 40 the body section 41 and a point 42 are really formed, torsional rigidity has flexibility in a point 42 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 41 and the point 42, it becomes possible to form the bore which becomes size comparatively. Moreover, like said catheter 30, while the above-mentioned catheter 40 makes quick responsibility of the point [as opposed to rotation of the body section 41 for change of the torsional rigidity of the body section 41 and a point 42] 42 as a loose thing, prevention of sudden a point 42 bending to the body section 41 of it is attained. Moreover, if it was in the above-mentioned catheter 40, since the edge by the side of the point 42 of wire layer 45B was pasted up on the inner tube part 43, it becomes possible to prevent the exfoliation from the inner tube part 43 of the edge of wire layer 45B in a manufacture phase.

[0023] Next, the manufacture approach of the above-mentioned catheter 40 is explained. First, extrusion molding of the flexible inner tube part 43 is carried out. Next, on an inner tube part 43, as shown in drawing 7 (A), the reinforcement layer 45 is formed further continuously. Here, wire layer 45A by which the reinforcement layer 45 was knit, and reinforcement layer 45B which is not knit are formed by turns. Next, after pasting up with adhesives the edge of wire layer 45B of the fixed section which should be removed on an inner tube part 43, a part of abbreviation center section of the above-mentioned wire layer 45B is removed as shown in drawing 7 (B). Next, extrusion molding of the outer tube part 44 is carried out to the top face of an inner tube part 43 and the wire layers 45A and 45B. Next, abbreviation pars intermedia X1 of a part with wire layer 45A Abbreviation pars intermedia X2 of a part without the reinforcement layer 45 The catheter 40 which cuts, makes a part with the wire layers 45A and 45B the body section 41, and uses a part without the reinforcement layer 45 as a point 42 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 45, and a part without the reinforcement layer 45, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 45 and the pars intermedia of a part without the reinforcement layer 45"] was provided here, if it was in this example etc., and it is a catheter 40 about the reinforcement layer 45. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 40.

[0024]

[Effect of the Invention] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point according to this invention as mentioned above While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The catheter which can prevent that sudden a point bends to the body section can be offered.

PRIOR ART

[Description of the Prior Art] The catheter 1 as shown in <u>drawing 1</u> is led to a guidewire etc., and is inserted into coelomata, such as a blood vessel, and attainment of it to the target part is enabled, the direction of the tip being controlled.

[0003] So, this catheter 1 is required to have the torsional rigidity which becomes size so that it may be possible to twist the base of the body section 2 and to orient that point 3. moreover, the point 3 -- the purpose part -- insertion -- it is possible to give an easy configuration easily, and flexibility is required of a point 3 so that the point 3 at the time of insertion may deform easily along with insertion path change of a blood vessel etc. and damage may not be done to walls, such as a blood vessel.

[0004] drawing 2 -- a point -- flexibility -- having -- and -- size -- the conventional catheter 4 which comes to have torsional rigidity is shown -- it is a fracture Fig. a part. The catheter 4 forms the body section 8 which is torsional rigidity and which becomes size by infixing the wire layer 7 between the flexible inner tube part 5 and the flexible outer tube part 6. Furthermore, the comparatively flexible point 9 is connected to the edge at which this catheter 4 removed the outer tube part 6 of the above-mentioned body section 8 in part.

[0005] drawing 3 -- a point -- flexibility -- having -- and -- size -- other conventional catheters 10 which come to have torsional rigidity are shown -- it is a fracture Fig. a part. After this catheter 10 had the 1st wire layer 12 formed from the end face of the flexible inner tube part 11 to tip this side, and it turns it up from that tip this side and it has the 2nd wire layer 13 again formed to a end face, it is having the flexible outer tube part 14 covered by the top face of an inner tube part 11 and both the wire layers 12 and 13.

EFFECT OF THE INVENTION

[Effect of the Invention] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point according to this invention as mentioned above, The bore which becomes size comparatively can be formed, and further, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, the catheter which can prevent that sudden a point bends to the body section can be offered.

TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] However, if it is in the above-mentioned catheter 4, a level difference is produced in the connection of the body section 8 and a point 9, it is difficult to perform insertion to a blood vessel etc. smoothly, and there is a possibility of producing a thrombus. Moreover, there is a possibility of producing balking among both, according to the faulty connection of the body section 8 and a point 9.

[0007] Moreover, since the reinforcement layer which consists of the 1st wire layer 12 and the 2nd wire layer 13 of a bilayer between the inner tube parts 11 and outer tube parts 14 from which the above-mentioned catheter 10 constitutes the body section is infixed, a catheter bore serves as smallness under the predetermined catheter outer diameter in which the thickness of a reinforcement layer becomes settled with insertion way bores, such as a blood vessel in which a large next door and a catheter are inserted. Moreover, since the thickness of the above-mentioned reinforcement layer is size, the level difference which comes size comparatively between the catheter outer diameter of the body section and the catheter outer diameter of a point is produced, and it becomes difficult to perform insertion to a blood vessel etc. Moreover, the above-mentioned catheter 10 is the top face of the inner tube part 11 which constitutes the body section, since it forms by turning up the 1st wire layer 12 and the 2nd wire layer 13, cannot form the whole continuously and cannot obtain the base material for catheters.

[0008] Moreover, while carrying out a loose thing for change of the torsional rigidity of the body section and a point and making quick responsibility of the point to rotation of the body section in order to improve the insertion workability into a blood vessel coelome if it is in a catheter, to enable prevention of sudden a point bending to the body section is desired.

[0009] While the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and abbreviation equalization of the outer diameter is carried out by the body section and the point, this invention While being able to form the bore which becomes size comparatively and making quick further responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing The purpose is carried out for offering the catheter which can prevent that sudden a point bends to the body section.

MEANS

[Means for Solving the Problem] This invention according to claim 1 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer. between inner tube parts and outer tube parts -- much more -- since -- further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer knit by ** by the side of the tip in the wire layer knit densely and the body section by the side of the end face in the body section.

[0011] This invention according to claim 2 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part. The becoming reinforcement layer is infixed and this point does not have the above-mentioned reinforcement layer, between inner tube parts and outer tube parts -- much more -- since --

further said reinforcement layer [in / this catheter has a point and the body section and / this body section] It is made to consist of a wire layer in which the end face side in the body section was knit, and a wire layer in which the tip side in the body section is not knit.

[0012] between inner tube parts and outer tube parts -- much more -- since -- the becoming reinforcement layer is infixed, this point does not have the above-mentioned reinforcement layer, but the edge by the side of the tip of said reinforcement layer is being further fixed to the inner tube part. [in / this invention according to claim 3 is a catheter which consists of an inner tube part which results at a tip from a end face, and an outer tube part which covers this inner tube part, and this catheter has a point and the body section, and / this body section] In addition, "immobilization" said here shall paste up the edge by the side of the tip of a reinforcement layer on an inner tube part with adhesives, and also laying under the inner tube welding and the wire layer which is a reinforcement layer further at an inner tube, applying heat shall include it.

OPERATION

[Function] According to this invention, there is the operation effectiveness of the following ** - **

** between inner tube parts and outer tube parts -- much more -- since -- since the becoming reinforcement layer is infixed and it was made for this point not to have the above-mentioned reinforcement layer, while the body section and a point are really formed, torsional rigidity has flexibility in a point greatly and an outer diameter is equalized by the body section and the point -- comparatively -- size -- it becomes possible to form a bore. [in / a catheter has a point and the body section and / this body section]

[0014] ** Since the reinforcement layer was constituted from two steps of what is not knit with two steps or the knit thing of ** as it is dense, while making quick responsibility of a point [as opposed to rotation of the body section for change of the torsional rigidity of the body section and a point] as a loose thing, it becomes possible to prevent that sudden a point bends to the body section.

[0015] ** The edge by the side of the tip of a reinforcement layer becomes possible [preventing the exfoliation from the inner tube part of the reinforcement layer edge in a manufacture phase] by coming to be fixed to an inner tube part.

EXAMPLE

[Example] The top view showing the catheter 30 which <u>drawing 4</u> (A) requires for the 1st example of this invention, the top view in which <u>drawing 4</u> (B) exfoliates and shows a part of outer tube part of this catheter 30, <u>drawing 5</u> (A), and (B) are the top views showing the manufacture process of this catheter 30.

[0017] a catheter 30 is shown in <u>drawing 4</u> (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- smallness -- a point 31 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 32 is really formed in shaft orientations. between the flexible inner tube part 33 in the body section 31 if it is in the above-mentioned catheter 30, and the flexible outer tube parts 34 -- much more -- since -- the becoming reinforcement layer 35 is infixed and the point 32 is formed according to the unification condition of an inner tube part 33 and an outer

tube part 34. Here, the reinforcement layer 35 is formed from wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side). The edge by the side of the point 32 of wire layer 35B is pasted up on the inner tube part 33.

[0018] While according to the above-mentioned catheter 30 the body section 31 and a point 32 are really formed, torsional rigidity has flexibility in a point 32 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 31 and the point 32, it becomes possible to form the bore which becomes size comparatively. If it is in the above-mentioned catheter 30 especially, by wire layer 35B knit by ** by the side of the point 32 in wire layer 35A knit densely and the body section 31 by the side of the anti-point 32 in the body section 31 (end face side) Since the reinforcement layer 35 was formed, while making quick responsibility of the point [as opposed to rotation of the body section 31 for change of the torsional rigidity of the body section 31 and a point 32] 32 as a loose thing It becomes possible to prevent that sudden a point 32 bends to the body section 31, and to prevent lock out generating of a catheter building envelope based on bending. Moreover, if it was in the above-mentioned catheter 30, since the edge by the side of the point 32 of wire layer 35B was pasted up on the inner tube part 33, it becomes possible to prevent the exfoliation from the inner tube part 33 of wire layer 35B in a manufacture phase.

[0019] Next, the manufacture approach of the above-mentioned catheter 30 is explained. First, extrusion molding of the flexible inner tube part 33 is carried out. Next, as shown in drawing 5 (A), the reinforcement layer 35 is continuously formed further in the top face of an inner tube part 33. here -- wire layer 35A with the eye of a network dense [the reinforcement layer 35] (for example, pitch P1 = 1mm), and the eye of a network -- ** (for example, pitch P2 = 10mm) -wire layer 35B is formed by turns. Next, after pasting up with adhesives the edge of wire layer 35B of the fixed section which should be removed on an inner tube part 33, a part of abbreviation center section of the above-mentioned wire layer 35B is removed as shown in drawing 5 (B). Next, extrusion molding of the flexible outer tube part 34 is carried out to the top face of an inner tube part 33 and the wire layers 35A and 35B. Next, abbreviation pars intermedia X1 of a part with wire layer 35A Abbreviation pars intermedia X2 of a part without the reinforcement layer 35 The catheter 30 which cuts, makes a part with the wire layers 35A and 35B the body section 31, and uses a part without the reinforcement layer 35 as a point 32 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 35, and a part without the reinforcement layer 35, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 35 and the pars intermedia of a part without the reinforcement layer 35"] was provided here, if it was in this example etc., and it is a catheter 30 about the reinforcement layer 35. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 30.

[0020] The top view showing the catheter 40 which <u>drawing 6</u> (A) requires for the 2nd example of this invention, the top view in which <u>drawing 6</u> (B) exfoliates and shows a part of outer tube part of this catheter 40, <u>drawing 7</u> (A), and (B) are the top views showing the manufacture process of this catheter 40.

[0021] a catheter 40 is shown in <u>drawing 6</u> (A) and (B) -- as -- die length L1 torsional rigidity -- comparatively -- size -- the body section 41 and die length L2 torsional rigidity -- comparatively -- smallness -- the point 42 is really formed in shaft orientations. between the flexible inner tube

part 43 in the body section 41 if it is in the above-mentioned catheter 40, and the flexible outer tube parts 44 -- much more -- since -- the becoming reinforcement layer 45 is infixed and the point 42 is formed in an inner tube part 43 according to the unification condition of an outer tube part 44. Here, the reinforcement layer 45 is formed from wire layer 45A by which the anti-point 42 side (end face side) in the body section 41 was knit, and wire layer 45B by which the point 42 side in the body section 41 is not knit. The edge by the side of the point 42 of wire layer 45B is pasted up on the inner tube part 43. Wire layer 45B which is not knit is prepared in a catheter shaft and parallel as drawing 7.

[0022] While according to the above-mentioned catheter 40 the body section 41 and a point 42 are really formed, torsional rigidity has flexibility in a point 42 greatly like said catheter 20 and abbreviation equalization of the outer diameter is carried out by the body section 41 and the point 42, it becomes possible to form the bore which becomes size comparatively. Moreover, like said catheter 30, while the above-mentioned catheter 40 makes quick responsibility of the point [as opposed to rotation of the body section 41 for change of the torsional rigidity of the body section 41 and a point 42] 42 as a loose thing, prevention of sudden a point 42 bending to the body section 41 of it is attained. Moreover, if it was in the above-mentioned catheter 40, since the edge by the side of the point 42 of wire layer 45B was pasted up on the inner tube part 43, it becomes possible to prevent the exfoliation from the inner tube part 43 of the edge of wire layer 45B in a manufacture phase.

[0023] Next, the manufacture approach of the above-mentioned catheter 40 is explained. First, extrusion molding of the flexible inner tube part 43 is carried out. Next, on an inner tube part 43, as shown in drawing 7 (A), the reinforcement layer 45 is formed further continuously. Here, wire layer 45A by which the reinforcement layer 45 was knit, and reinforcement layer 45B which is not knit are formed by turns. Next, after pasting up with adhesives the edge of wire layer 45B of the fixed section which should be removed on an inner tube part 43, a part of abbreviation center section of the above-mentioned wire layer 45B is removed as shown in drawing 7 (B). Next, extrusion molding of the outer tube part 44 is carried out to the top face of an inner tube part 43 and the wire layers 45A and 45B. Next, abbreviation pars intermedia X1 of a part with wire layer 45A Abbreviation pars intermedia X2 of a part without the reinforcement layer 45 The catheter 40 which cuts, makes a part with the wire layers 45A and 45B the body section 41, and uses a part without the reinforcement layer 45 as a point 42 is obtained. It compares with cutting in the boundary section of a part with the reinforcement layer 45, and a part without the reinforcement layer 45, since the technical matter which was not seen at all conventionally [of "having cut the pars intermedia of a part with the reinforcement layer 45 and the pars intermedia of a part without the reinforcement layer 45"] was provided here, if it was in this example etc., and it is a catheter 40 about the reinforcement layer 45. Two duty continuation formation can be carried out and the merit according to rank that productivity can be improved is. That is, according to the above-mentioned manufacture approach, formation becomes possible continuously for high productivity about a catheter 40.

DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1] Drawing 1 is the top view showing a common catheter.

[Drawing 2] drawing 2 shows the catheter concerning the conventional example -- it is a fracture

Fig. a part.

[Drawing 3] drawing 3 shows the catheter concerning other conventional examples -- it is a fracture Fig. a part.

[Drawing 4] They are the top view showing the catheter which drawing 4 (A) requires for the 1st example of this invention, and the top view in which drawing 4 (B) exfoliates and shows a part of outer tube part of this catheter.

[Drawing 5] Drawing 5 (A) and (B) are the top views showing the manufacture process of this catheter.

[Drawing 6] They are the top view showing the catheter which drawing 6 (A) requires for the 2nd example of this invention, and the top view in which drawing 6 (B) exfoliates and shows a part of outer tube part of this catheter.

[Drawing 7] Drawing 7 (A) and (B) are the top views showing the manufacture process of this catheter.

[Description of Notations]

30 40 Catheter

31 41 Body section

32 42 Point

33 43 Inner tube part

34 44 Outer tube part

35 45 Reinforcement layer

35A, 35B, 45A, 45B Wire layer

[Translation done.]